IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

IN RE:	:	
	:	No. 3:06-MD-1760
AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION	:	JUDGE CAMPBELL
(MDL No. 1760)	:	MAGISTRATE JUDGE BROWN
This Document Relates to: Case No.: 3:06-CV-00369 (Parmentier/Johnson)	:	

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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Attorneys for Plaintiff Judith Parmentier

Plaintiff Judith Parmentier ("Plaintiff")[1] respectfully submits this memorandum in opposition to defendant Novartis Pharmaceuticals Corporation's ("Defendant" or "Novartis") motion for summary judgment. As shown below, because Plaintiff has proffered more than sufficient evidence in support of her claims, Defendant's motion should be denied.

PRELIMINARY STATEMENT[2]

In this product liability action, Plaintiff alleges, and the evidence will show, that Linda Johnson developed osteonecrosis of the jaw ("ONJ") as a result of being prescribed and treated with Defendant's drugs Aredia and Zometa. ONJ is a serious, painful and debilitating medical condition in which part of the individual's jaw bone has died. In this case, Linda Johnson's ONJ appeared on both sides of her lower jaw and ultimately necessitated a debridement. As Linda Johnson's treating oral and maxillofacial surgeon, Dr. Begley explained that during the debridement, he used cutting tools to remove dead jaw bone from both sides of Linda Johnson's lower jaw until he reached bleeding bone. Begley Dep. at 25-26.

Plaintiff filed suit against Defendant in federal court, challenging Defendant's development, testing, manufacturing, labeling and marketing of Aredia and Zometa. Specifically, Plaintiff's common law claims include claims for strict product liability (design defect), strict product liability (failure to warn), negligence, breach of express warranty and

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[1] Judith Parmentier, Linda Johnson's sister, was substituted as the personal representative of the estate of Linda Johnson after she died.

[2] The following documents are attached hereto: (Exhibit 1) Affidavit of Ramin Shabtaie, D.D.S. ("Shabtaie Aff."), (Exhibit 2) Excerpts from the Transcript of the Deposition of Dr. Shabtaie ("Shabtaie Dep."), (Exhibit 3) Excerpts from the Transcript of the Deposition of Dr. Begley ("Begley Dep."), (Exhibit 4) Excerpts from the Transcript of the Deposition of Dr. Peters ("Peters Dep.").

breach of implied warranty. This case was subsequently transferred into this multi-district product liability litigation.

Defendant now moves for summary judgment on all claims, arguing that Plaintiff has failed to produce sufficient evidence to meet her burden of proof. As shown below, the evidence developed during this multi-district litigation, and in the Johnson case specifically, is more than sufficient for a reasonable jury to find in Plaintiff's favor on each cause of action.

ARGUMENT

I. LEGAL STANDARD

Defendant has moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. Under Rule 56(c), summary judgment "should be rendered if the pleadings, the discovery and the disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

As the Supreme Court explained, and Rule 56(c) suggests, "at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty lobby, Inc.*, 477 U.S. 242, 229 (1986). The question before the district court is simply "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52 (emphasis added). In other words, "the judge must ask himself not whether he thinks the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." *Id.* at 252.

In deciding a summary judgment motion, a district court must bear in mind that "credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . .." *Id.* at 255. As the Sixth Circuit stated even more clearly, "[i]n reviewing a summary judgment motion, credibility judgments and weighing of the evidence are prohibited." *Centra, Inc. v. Estrin*, 538 F.3d 402, 412 (6th Cir. 2008); *see also*, *Patterson v. Hudson Area Schools*, 551 F.3d 438, 445 (6th Cir. 2009). Not surprisingly, therefore, "[i]t is an error for [a] district court to resolve credibility issues against [a] nonmovant." *Centra*, 538 F.3d at 412.

Furthermore, in regard to a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255. *See also*, *Patterson*, 551 F.3d at 444; *Centra*, 538 F.3d at 412. A district court's "job is to look at the facts and consider them in the light most favorable to the nonmoving party, regardless of [the court's] own personal views of how much credence [the court] would give a particular piece of evidence . . .." *Patterson*, 551 F.3d at 446. In fact, "[i]f, as to the issue on which summary judgment is sought, there is any evidence in the record from which a reasonable inference could be drawn in favor of the opposing party, summary judgment is improper." *Hetchkop v. Woodlawn at Grassmere, Inc.*, 116 F.3d 28, 33 (2d Cir. 1997) (citations omitted).

Finally, as the Supreme Court noted in discussing the standard to be applied to a summary judgment motion:

> Neither, do we suggest that the trial courts should act other than with caution in granting summary judgment or that the trial court may not deny summary judgment in a case where there is reason to believe that the better course would be to proceed to a full trial.

Anderson, 477 U.S. at 255.

In the present case, there is more than sufficient evidence for a jury to find for Plaintiff. A reasonable jury could find that Linda Johnson developed ONJ as a result of her exposure to Aredia and/or Zometa, that Aredia and/or Zometa were defective, that Defendant's warnings were inadequate, and that Defendant breached its warranties. Accordingly, Defendant's motion for summary judgment should be denied.

II. CAUSATION

Defendant moves for summary judgment on the grounds, in part, that Plaintiff lacks admissible expert testimony on case specific causation, i.e., that Aredia and/or Zometa caused Linda Johnson's ONJ. Defendant's Memorandum at 10-12. To the contrary, as the evidence discussed below shows, Plaintiff has proffered more than sufficient admissible evidence for a reasonable jury to find in her favor on the issue of case-specific causation.

A. Proving Causation Under Missouri Law

In Missouri, "[t]o establish causation, Plaintiff must show that [defendant's] conduct was both the cause in fact and the proximate or legal cause of [plaintiff's] injury." *Strong v. American Cyanamid Co.*, 261 S.W.3d 493, 506 (Mo. Ct. App. 2008). "In other words, the plaintiff must put forth sufficient evidence for a jury to conclude that the product was capable of causing her injuries, and that it did." *Bonner v. ISP Tech., Inc.*, 259 F.3d 924, 928 (8th Cir. 2001).

Under Missouri law "[t]o establish causation . . . the plaintiff [is] required to present substantial evidence from which a jury could conclude that the injuries . . . and damages to the plaintiff resulted from" the defendant's product. *Kircher v. Purina Mills, Inc.*, 775 S.W.2d 115,

117 (Mo. 1989). *See also Tenbarge v. Ames Taping Tool Sys., Inc.*, 128 F.3d 656, 659 (8th Cir. 1997). Although "[e]vidence of causation must be based on probative facts not on mere speculation or conjecture . . . plaintiff is not required to exclude all other possible causes or to prove an absolutely positive causal connection." *Kircher*, 775 S.W.2d at 117. *See also Peters v. General Motors Corp.*, 200 S.W.3d 1, 18 (Mo. Ct. App. 2006) (Plaintiff's "burden of proof did not require that his evidence exclude all possibility of another cause . . . nor was he required to present undisputed evidence."). "Normally, the trier of fact will decide causation, especially where reasonable minds could differ." *Strong*, 261 S.W.3d at 506.

B. Plaintiff Has Proffered Sufficient Admissible Evidence on Case-Specific Causation to Raise a Question of Fact

In support of its motion for summary judgment, Defendant argues that this Court should exclude the specific causation opinions of Plaintiff's retained and non-retained experts. In other words, Defendant repeats the arguments it makes in its *Daubert* motion. Accordingly, Plaintiff respectfully refers this Court to her opposition to Defendant's *Daubert* motion and incorporates by reference the arguments and evidence she made therein. Some of those arguments are repeated here for the Court's convenience.

Plaintiff intends to rely, in part, on the expert testimony of Dr. Ramin Shabtaie to prove case-specific causation. Dr. Shabtaie was retained and designated as an expert in this case; he provided an expert affidavit; and was deposed by Novartis. Plaintiff also intends to rely, in part, on the testimony of Dr. Randal Begley and Dr. Ray Peters to prove case-specific causation. Dr. Begley treated Ms. Johnson's ONJ and Dr. Peters was Ms. Johnson's oncologist; he prescribed and ultimately stopped the Aredia and Zometa treatments. Neither doctor has been retained as an

expert in this case; however, both were designated as non-retained experts by Plaintiff (as well as by Defendant) and both have been deposed in this case.

Dr. Shabtaie. In this case, Dr. Shabtaie concluded, to a reasonable degree of medical certainty, that Linda Johnson developed ONJ as a result of being treated with a bisphosphonate, in this case Zometa (and perhaps Aredia as well). Shabtaie Aff. at ¶ 10.

In connection with his work in this case, Dr. Shabtaie reviewed Ms. Johnson's relevant medical records, including the charts and records of Dr. Ray Peters, Dr. Laura Holmes, Dr. Donna Almond, Dr. Dennis Leutkemeyer, Dr. Benny Bell, and Dr. Randall Begley. *Id.* at ¶ 13. Dr. Shabtaie also reviewed the transcripts of the depositions of Dr. Begley and Dr. Bell. *Id.* Dr. Shabtaie relied on his more than ten years of experience as an oral and maxillofacial surgeon (and his training), his experience evaluating and treating patients with bisphosphonate related ONJ (as well as patients with necrotic bone in their jaws for other reasons), the available medical literature on bisphosphonate related ONJ, his knowledge of bone biology, and information he learned through collaborations with his colleagues. Shabtaie Aff. at ¶¶ 5-9.

In reaching his conclusions about Ms. Johnson, Dr. Shabtaie performed a differential diagnosis. Shabtaie Aff. ¶ 20. Performing differential diagnoses is something that Dr. Shabtaie does routinely in his practice. Shabtaie Dep. at 75-77. In this case, Dr. Shabtaie considered other possible explanations for Ms. Johnson's ONJ in addition to her treatment with Aredia and Zometa, and ruled them out. Shabtaie Aff. at ¶ 20. Among the other explanations considered by Dr. Shabtaie was radiation. *Id.* Dr. Shabtaie ruled out radiation because there is no evidence that Ms. Johnson received radiation therapy to her jaw. *Id.* Moreover, there is no evidence that Ms. Johnson suffered from mucositis or xerostomia (signs of excessive exposure to radiation). *Id.*

Dr. Begley and Dr. Peters. Dr. Begley is a practicing oral and maxillofacial surgeon and has been since 2001. Begley Dep. at 6-7. Since he began practicing, Dr. Begley has treated five or six patients with BRONJ, including Ms. Johnson. Begley Dep. at 27. Dr. Begley treated Ms. Johnson beginning in January, 2004. Begley Dep. at 9, 14. She was referred by her oncologist because of exposed bone in her lower jaw. Begley Dep. at 10. Dr. Begley ultimately saw Ms. Johnson seven times and performed a debridement on both sides of her lower jaw. Begley Dep. 22, 25-26. Because Ms. Johnson was Dr. Begley's first patient with BRONJ, he did not recognize it at that time. Begley Dep. at 27. Subsequently, however, based on what he has learned (both from treating other patients and continuing education), Dr. Begley testified that he believes that Zometa was a cause of Ms. Johnson's ONJ. Begley Dep. at 29-30.

Dr. Peters is a practicing medical oncologist and has been for more than 20 years. Peters Dep. at 5-10. He is Board certified in internal medicine and medical oncology. *Id.* at 6. Dr. Peters began treating Linda Johnson in November, 2001 (*Id.* at 16) and continued to provide care to her until she passed away in 2007. While treating Linda Johnson, Dr. Peters concluded that she had ONJ and that it was caused by her treatment with bisphosphonates, i.e., Aredia and Zometa. *Id.* at 67-69.

According to Defendant, in order to prevail, Plaintiff must present expert evidence on specific causation "to a reasonable degree of certainty." Defendant's Memorandum at 11-12. If Defendant is suggesting that a witness must state that his or her opinion is given to "a reasonable degree of certainty," and therefore this Court must exclude Plaintiff's experts' testimony, it misstates the law. The general rule that expert opinion testimony be given to "a reasonable degree of certainty," is intended to keep from the jury equivocal opinions and testimony. *See*

Abbott v. Haga, 77 S.W.3d 728, 732 (Mo. Ct. App. 2002), *Scott v. Blue Springs Ford Sales, Inc.*, 215 S.W.3d 145, 178-79 (Mo. Ct. App. 2006). The Supreme Court of Missouri, however, has made it clear that "the precise words used by an expert witness do not necessarily 'render his testimony inadmissible if he intended to express his opinion or judgment." *Bynote v. National Super Mkt.*, 891 S.W.2d 117, 125 (Mo. 1995). *See also Williams v. Daus*, 114 S.W.3d 351, 363 (Mo. Ct. App. 2003) ("In our review of the record, we determine that Respondent's expert witnesses intended to express their respective opinions and/or judgments regarding Respondent's physical condition . . . despite the fact that they did not always use the assertedly talismanic phrase, within a 'reasonable degree of medical certainty.'")

There is nothing equivocal about Dr. Shabtaie's opinions in this case. Nor about the conclusion's reached by Dr. Begley and Dr. Peters. All three of these doctors concluded that Linda Johnson's ONJ wascaused by her use of Aredia and/or Zometa.

Because Plaintiff has, over the course of this multi-district litigation as well as in the Johnson case, developed, produced and proffered sufficient evidence of case-specific causation for a reasonable jury to find in her favor, Defendant's summary judgment motion should be denied.

III. FAILURE TO WARN CLAIM

Defendant argues that Plaintiff's failure to warn claim, under Missouri law, fails because: (i) Plaintiff cannot show that Novartis knew or should have known about the risk of ONJ before September 2003, (ii) its warnings were adequate after September 2003, and (iii) Plaintiff cannot prove that an "adequate" warning would have altered Dr. Peters' or Ms. Johnson's behavior. Defendant's Memorandum at 12-17.

Defendant's warnings, as shown by the evidence proffered by Plaintiff, are not (and were not) adequate. Moreover, Plaintiff is entitled to a rebuttable presumption that an adequate warning would have been read and heeded. Defendant has offered no evidence to rebut that presumption.. Therefore, Defendant's summary motion judgment should be denied.

A. Defendant Had a Duty to Warn Before September 2003

There is more than sufficient evidence for a reasonable jury to conclude that Defendant knew or should have known before September 2003 that its drugs, Aredia and Zometa, could cause ONJ. Plaintiff respectfully incorporates by reference the information contained in Plaintiff's Statement of Facts in Opposition to NPC's Motion for Summary Judgment (filed contemporaneously herewith). Novartis knew every item up to number forty before September, 2003. Below is a summary of what NPC knew or should have known:

a. The diseases osteopetrosis and pycnodysostosis mimic the mechanism of action of Aredia and Zometa, and each cause ONJ;

b. Animal models showed ONJ in rats exposed to bisphosphonates as early as 1983;

c. Cases of ONJ appeared in the Aredia and Zometa clinical trials but were unrecognized or ignored by Novartis, and the initial product labels/package inserts contained no information regarding ONJ; and,

d. Novartis knew, or should have known, about Phossy jaw, a condition which afflicted many persons working in match factories in the 1800s and early 1900s.

The foregoing is just a sample of the voluminous material that the Court has already considered and deemed sufficient to overcome Novartis's summary judgment motion that its warnings were adequate. Plaintiff incorporates by reference, pursuant to Rule 10(c), Federal Rules of Civil Procedure, Plaintiffs' opposition to Novartis's motion for summary judgment on

the adequacy of the Aredia and Zometa warnings [DE 2614] and materials cited therein in further opposition to Novartis's assertions that its warnings were adequate and timely in this case.

Because the evidence and testimony is more than sufficient for a reasonable jury to conclude that Defendant had a duty to warn and failed to provide an adequate warning, Defendant's motion for summary judgment should be denied.

B. Defendant's Warnings Were Not Adequate

While Defendant asserts that its "warning" about ONJ and bisphosphonates was adequate, it makes no effort in this motion to support that claim. In fact, in its brief, Defendant does not even discuss the actual language it claims to be adequate. Nor does Defendant identify any specific evidence or testimony it believes supports its adequacy claim. Instead, Defendant refers the Court to its Motion for Summary Judgment on Adequacy of Aredia and Zometa Warnings filed in the main multi-district matter. Plaintiff, therefore, as noted above, respectfully refers the Court to, and incorporates by reference herein, the Plaintiffs' opposition to Novartis's motion for summary judgment on the adequacy of the Aredia and Zometa warnings [De 2614].

Plaintiff intends to rely, in part, on the testimony of Dr. Parisian, Dr. Skubitz and Dr. Vogel to prove that Defendant's warning were inadequate. This testimony, discussed here, is sufficient to raise a triable issue of fact regarding the adequacy of Defendant's warnings.

Dr. Parisian. Dr. Parisian has a medical degree and is board certified in anatomic and clinical pathology. (Parisian Report ¶¶ 1-3, First Germany Dec. Ex. 16 [DE 2457].) From 1991 to 1993, Dr. Parisian was an FDA Medical Officer in the Office of Health Affairs. (*Id.*) Dr. Parisian also served as a Commissioned Officer in the United States Public Health Service from

1991 to 1995. (*Id.*) In 1995, Dr. Parisian founded MD Assist, Inc., a regulatory and medical consulting firm specializing in matters involving the regulation of products by the FDA. (*Id.*)

Dr. Parisian will testify, among other things, that Defendant failed to provide fair and balanced information about Zometa to health care providers. (*Id.* at pp. 113-120.) For example, Novartis failed to provide all material facts relating to adverse events and the difference in risks of ONJ between Zometa and Aredia (a precursor Novartis bisphosphonate). (*Id.*) Dr. Parisian also states that Defendant failed to update its drug labeling with adequate information and warnings. (*Id.*)

Dr. Vogel. As noted above, Dr. Vogel has been a practicing physician, specializing in the fields of hematology and medical oncology, for thirty five years. He is board certified in internal medicine and in the internal medicine subspecialties of hematology and medical oncology. Dr. Vogel has been prescribing bisphosphonates to his patients for ten years and has prescribed bisphosphonates to hundreds of patients. (Vogel Report ¶¶ 1, 11-17, First Germany Dec. Ex. 27 [DE 2457].)

Dr. Vogel will testify, among other things, to what Novartis told treating physicians about the risks of ONJ and to how that information was false and/or misleading. (*Id.* at ¶¶ 27-55.) For example, Dr. Vogel notes that physicians were originally told that intravenous bisphosphonates had the same safety and side effect profile as oral bisphosphonates but that, in fact, intravenous bisphosphonates in particular cause ONJ. (*Id.* at ¶¶ 28-29.) In addition, Dr. Vogel addresses the label changes and letters sent to doctors in 2003 and 2004 and concludes that these materials were unclear and misleading. (*Id.* at ¶¶ 30-41.) According to r. Vogel, the causal relationship between intravenous bisphosphonates, such as Zometa, and ONJ was obscured by presenting a

number of other possibilities, many of which turned out to be red herrings. (*Id.* at ¶¶ 39-40c.)

Dr. Skubitz. Dr. Skubitz, discussed above, is board certified in internal medicine and medical oncology. He regularly sees patients in the oncology clinic at the University of Minnesota Medical School and has prescribed Zometa. He also conducts research on cancer and clinical cancer therapy.

`Dr. Skubitz, like Dr. Vogel, goes through various documents produced by Novartis, including Form Letters for health care providers, White Papers, Label Changes, Publications and marketing Documents. (Skubitz Report, ¶¶ 97-124, First Germany Dec. Ex. 23 [DE 2457].) Dr. Vogel will testify, among other things, that in each instance the materials prepared by Novartis were, at best, misleading. (*Id.* at ¶¶ 101, 104, 110, 114, 118, 120, 124) According to Dr. Skubitz the Novartis materials are misleading in that they, among other things, downplay the role of bisphosphonates as a cause of ONJ, suggest that there are other well documented causes of ONJ, and minimize the incidence of ONJ. (*Id.*)

As this evidence and testimony shows, a reasonable jury could conclude that Defendant failed to provide adequate warnings and, therefore, Defendant's motion for summary judgment should be denied.

C. An Adequate Warning May Have Prevented Linda Johnson's Injuries

As Defendant notes, under Missouri law causation is a required element of failure to warn in a product liability case. *See Mothershead v. Greenbriar Country Club, Inc.*, 994 S.W.2d 80, 89 (Mo. Ct. App. 1999). Proof of causation requires both "proof of a proximate causal link between [plaintiff's] injury and the product allegedly lacking a warning or having an inadequate warning . . .[and] that a warning would have altered the behavior of those involved in the

accident." *Id.* According to Defendant, Plaintiff must show that a different warning "would have altered Dr. Peters' or [the prescriber] or Ms. Johnson's behavior." Defendant's Memorandum at 16 (emphasis added).

Defendant's statement of the law, however, is, at best, incomplete. First, under Missouri law Plaintiff is entitled to a rebuttable presumption that an adequate warning would be heeded. *See Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992); *Hill v. Air Shields, Inc.*, 721 S.W.2d 112, 118 (Mo. Ct. App. 1986); *Duke v. Great W. Mfg. Co.*, 660 S.W.2d 404, 419 (Mo. Ct. App. 1983). Defendant makes no mention of this presumption. In any event, a "plaintiff does not fail to make a submissible case merely because it is not demonstrated with certainty that an adequate warning would have prevented plaintiff's injuries." *Griggs v. Firestone Tire & Rubber Co.*, 513 F.2d 851, 861 (8th Cir. 1975); *see also Hill*, 721 S.W.2d at 119, *Racer v. Utterman*, 629 S.W.2d 387, 394 (Mo. Ct. App. 1981). Moreover, in general, "[t]he determination of proximate cause is ordinarily reserved for the jury . . .." *Griggs*, 513 F.2d at 861; *see also Duke*, 660 S.W.2d at 419 ("The evidence shows no more than a 'general awareness' of the danger . . . and does not indicate knowledge of the specific danger [thus] [t]he question was one for the jury."), *Racer*, 629 S.W.2d at 394 ("In the absence of compelling evidence establishing that the absence of a warning did not cause the injury the causation question becomes one for the jury.")

Although Defendant does not discuss the presumption that an adequate warning would have been heeded and, thus makes no effort to overcome that presumption, it does claim that there is no evidence that Dr. Peters would not have prescribed Aredia or Zometa. Although Dr. Peters may not have testified that he would not have prescribed Aredia and Zometa, he made it

very clear that he would have done a number of things differently, and does so today. He testified:

> Q. What side effects do you discuss today?
> A. Osteonecrosis of the jaw prominently. Renal dysfunction. Hypoglycemia. Pain.
>
> * * *
>
> Q. What do you think you would have discussed with her [Ms. Johnson]? Would you have discussed all of those except osteonecrosis of the jaw?
> A. I would assume. And I would have also discussed with her potential benefit of treatment.
>
> * * *
>
> Q. In addition to discussing the potential side effect as stated by you has you practice changed at all? Have you done anything different in your practice?
> A. Yes.
> Q. Tell me what that is?
> A. We dose bisphosphonates less frequently.
> Q. What do you mean you dose them less frequently?
> A. Back in those days you were giving them every month and now we tend not to do that.
> Q. What do you do now?
> A. Well, we dose it less frequently than every month. Maybe every other month. Maybe every third month. But, it depends in part on how long they are going to get them. So that's one thing. We dose them less frequently. Another thing that we do is we try to have all dental work done ahead of time before bisphosphonates is administered. We monitor renal function very closely. We monitor jaw discomfort very closely.
>
> * * *
>
> Q. What do you tell your patients about dental work?
> A. Well, make sure – there are those who do not have the means or the ability to get dental work done. But, we caution them. We attempt to get them to someone who can do the dental work if we can get that done.

* * *

Q. Do you do anything to caution patients about having dental procedures prior to administering the bisphosphonates?
A. Absolutely.
Q. What do you tell them?
A. I tell them not to have any dental work done without – once it is started without consulting with us.

Peters Dep. at 36-38. All of these behaviors started after Linda Johnson developed ONJ (Peters Dep. at 70-72) and evidence what might have been if Defendant had properly warned about the risk of ONJ.

Ultimately, the question of whether an adequate warning would have been heeded in this case is properly left to a jury. The evidence, certainly, is insufficient for Defendant to meet its burden to rebut the presumption that a proper warning would have been heeded. Accordingly, Defendant's motion for summary judgment should be denied.

IV. DESIGN DEFECT CLAIM[3]

Defendant argues that Plaintiff's design defect claim fails as a matter of law under Missouri law because it is entitled to the protection of comment k to the Restatement (Second of Torts § 402A. Defendant's Memorandum at 17-18. As Defendant acknowledges, however, it bears the burden of proving that its drug is entitled to comment k protection.

At the outset, it should be noted that "[c]omment k requires that the product be 'properly prepared, and accompanied by proper directions and warning ....' " *See Pollard v. Ashby*, 793 S.W.2d 394, 400 (Mo. Ct. App. 1990). In other words, "[c]ases involving . . . inadequate

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[3] Plaintiff is not pursuing a manufacturing defect claim.

warnings do not involve comment k protection." *Id.* (citation omitted). In addition, in the context of a drug, a manufacturer is protected by comment k only if it can show (i) that its drug's risks are unavoidable, and (ii) the overall benefit of the drug outweighs the risks. *Id.* Courts in Missouri have found that "application of Comment (k) to [a drug] is a question of fact." *Wright v. American Home Prods. Corp.*, No. 06-CV-4183-NKL, 2008 WL 1820902, at *3 (W.D. Mo. Apr. 18, 2008), *see also Hill v. Wyeth*, No. 4:03CV1526 JCH, 2007 WL 674251, at *5 (E.D. Mo. Feb. 28, 2007), *LaChance v. American Home Prods. Corp.*, No. 01-0890-CV-W-ODS, 2006 WL 89850, at *4-5 (W.D. Mo. Jan. 13, 2006).

Defendant has failed to meet its burden to prove that comment k applies. First, in support of its summary judgment motion, Defendant has offered no evidence that its warnings were adequate. Moreover, as shown above, there is a question of fact as to whether Defendant's warnings were adequate. Accordingly, Defendant has failed to prove that comment k even applies in this case. In addition, Defendant has not shown any evidence of a risk-benefit analysis concluding that Aredia and Zometa's benefits outweigh their risks of causing ONJ. Instead, Defendant simply asserts this as a fact.

Because Defendant has not met its burden of proof with regard to comment k, its motion for summary judgment with regard to Plaintiff's strict liability design defect claim should be denied.

V. BREACH OF IMPLIED WARRANTIES CLAIM[4]

Defendant argues that Plaintiff's implied warranties claim fail as a matter of law under Missouri law because Plaintiff has no evidence that Zometa was not "merchantable." Defendant is wrong.

An implied warranty of merchantability is an unwritten guarantee that the product conforms to the representations, express and implied, on the label. Plaintiff here acknowledges that Missouri's implied warranty claims regarding products are governed by Missouri Statute § 400.2-314. Section 400.2-314 sets forth six criteria for evaluating the merchantability of products. The requirements are inclusive, meaning that Novartis must satisfy all six to defeat a claim for breach of an implied warranty.

One of the requirements for merchantability – not discussed by Defendant - is that the product be "adequately contained, packaged and labeled" as the agreement may require. Section 400.2-314(e) R.S. Mo. For the reasons set forth in the Plaintiffs' Steering Committee's brief in opposition to Novartis' warnings brief, and for the reasons set forth above in this brief, Novartis' product was unmerchantable because Novartis failed to provide adequate warnings concerning the adverse side effects caused by Aredia and Zometa, specifically ONJ. Novartis had reasonable knowledge that patients using bisphosphonate therapy were presenting with ONJ at an alarming rate, but instead of issuing a comprehensive and meaningful warning, the company misled the medical community by placing a fictitious set of alternate risk factors on the Aredia and Zometa labels.

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[4] Plaintiff is not pursuing a claim for breach of express warranty.

CONCLUSION

Based on the foregoing this Court should deny Novartis' motion for summary judgment.

Dated: August 1, 2011

Respectfully Submitted,

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Counsel for Plaintiff Judith Parmentier

CERTIFICATE OF SERVICE

On this 1st day of August, 2011, I certify that I served all counsel of record, including counsel for defendant, by filing the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT** by using this Court's ECF system.

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